



10/Reply Brief
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Attorney's Docket No. LIFE-005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	
)	
DEBRECZENY, MARTIN P.)	Group Art Unit: 2877
)	
Application No.: 09/586,692)	Examiner: Turner, Samuel A.
)	
Filed: June 1, 2000)	
)	
For: DUAL BEAM FTIR METHODS AND)	
DEVICES FOR USE IN ANALYTE DETECTION IN)	
SAMPLES OF LOW TRANSMISSIVITY)	

REPLY BRIEF FOR APPELLANT

Mail Stop: Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This brief is submitted in reply to the Examiner's Answer dated March 4., 2003 in support of the rejection of claims 1-28.

No fee is believed necessary in connection with this paper. However, the Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required. This paper is submitted in triplicate.

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I. Formal Matters

Regarding each of the Real Party in Interest, Related Appeals and Interferences, Status of Claims, Status of Amendments and Summary of the Invention, reference is made to Appellant's Appeal Brief filed December 23, 2002 setting these matters forth, which Appeal Brief is incorporated by reference herein in that regard.

II. The Issues

The issues on appeal include: whether Claims 1-10, 12, 13 and 21-28 are patentable over Mattson et al.; whether Claims 1-13, and 21-28 are patentable over Griffiths et al. (Chapter 8-AO); and finally whether Claims 14-20 are patentable over Griffiths et al. (Chapter 8-AO).

III. Grouping of Claims

Claims 1, 6, 14-20 and 21 do not stand or fall together and have been argued separately below. Claims 2-5 stand or fall with Claim 1, Claims 7-20 stand or fall with Claim 6, and Claims 22-28 stand or fall with Claim 21.

IV. Argument

Appellants maintain for the reasons below and as previously submitted, especially in Appellants' Appeal Brief, that the rejections of Claims 1-10, 12, 13 and 21-28 under 35 U.S.C. §102(b) as being clearly anticipated by Mattson et al. is in error because Mattson does not teach or disclose every element required by the claims .

Appellants further maintain for the reasons below and as previously submitted, that the rejections of Claims 1-13, and 21-28 as being clearly anticipated by Griffiths et al. is in error because Griffiths et al. does not teach or disclose every element of the present invention.

Additionally, Appellants maintain for the reasons previously submitted in Appellants' Appeal Brief that the rejections of Claims 14-20 as being unpatentable over Griffiths et al. is in error.

A. Answer Treatment of Claims 1 and 6 in View of Mattson et al.

In support of the Examiners' comparison of the limitations of claims 1 and 6 with Mattson et al. in attempting to meet the limitation of claim 1 and 6 requiring a sample of low transmissivity, the sample provided as 26b in the reference was noted. Regarding this, it was stated that a "dual beam nulling interferometric spectrometer is not limited by the transmissivity of the sample and thus anticipates samples of the full range of transmissivity."

Irrespective of the merit of this assertion (see, treatment in Appellants' Appeal Brief), stating in the negative that something is not limited in one regard does not prove the positive that this something affirmatively teaches or discloses the opposite. Rather, as in the present case, such teaching in a reference merely represents silence on the point.¹ The Examiner has cited no authority in support of his repeated assertion that the alleged lack of limitation of sample type in Mattson et al. provides adequate legal support for a case of anticipation.

All that has been attempted by the Examiner is a theoretical explanation as to why the reference is not limited in use to samples of high transmissivity. Whether right or wrong, failing an appropriate framework in which to reject the claims (namely law standing for the proposition that the supposedly generic disclosure anticipates the specific requirements of the claims), the rejection should not stand.

Further, Appellants note that the claims are not directed to samples of a "full range of transmissivity" as stated by the Examiner, which could properly be anticipated as suggested. Claims 1, 6 and those dependent therefrom make no claim to a genus of samples of any (or all) transmissivity, but are only directed to the individual species of low transmissivity samples – something that the (at-best) generic disclosure in Mattson et al. cannot be said to anticipate under well-established law regarding genus/species situations.² Additional discussion in this regard is presented in the Appeal Brief to which the Examiner's Answer was completely silent.

¹ At page 9 of his Answer, the Examiner acceded to the point that the reference is so-silent.

² *Imperial Chem. Indus. v. Henkel Corp*, 545 F. Supp. 635, 646 (D. Del. 1982) citing Chisum, *Patents* §3.02[2]. See also, referenced Chisum section.

For at least these reasons, the rejection of the pertinent claims and continued line of reasoning expressed in the Examiner's Answer is believed incorrect.

B. Answer Treatment of Claim 21 in View of Mattson et al. and Griffiths et al.

In support of the rejections of claim 21, the Examiner stated that the "transmissivity of the sample is mere intended use and does not further limit the claim." To the contrary, as asserted in Appellant's Appeal Brief:

Read in accordance with 35 U.S.C. §112, ¶6 – as the various "mean for" clauses in claims 21-28 must be – the claims are distinguished over Mattson et al. and Griffiths et al. for such reasons as equally applicable to claims 1-13 as argued in the context of claims 1 and 6 above. In that respect, the clause requiring "means for producing a sample beam and a reference beam from said forward and backward beams," necessitates a low transmissivity sample in the system.

In short, the "means" language must be treated in accordance with 35 U.S.C. §112, ¶6. Accordingly, the claim 21 and those dependent therefrom are positively limited as including a sample of low transmissivity as part of the stated "means." As argued variously through out this paper and in previous submissions, neither reference's teachings are adequate to meet such claim limitations.

How or why the Examiner regards the sample of low transmissivity as a mere indication of intended use is totally unclear to Appellants. No authority has been cited by the Examiner in this regard.³ Nor has any reasoning been provided – except maybe for some reference to claim preambles which has nothing to do with Appellants' means-based arguments. Indeed, it is believed the Examiner's position is unfounded and incorrect as is the treatment of the low-transmissivity nature of the sample itself as commented upon above and further below.

³ It does not appear to Appellants that the Examiner has even made a recognizable attempt to follow the examination guidelines for means plus function claim limitations as set forth in MPEP §§2181-2183, and especially §2183 entitled, "*Making a Prima Facie Case of Equivalence*" as pertinent to the element-for-element equivalence comparison required.

C. Examiner Answer Treatment of Claims 1 and 6 in View of Griffiths et al.

Claims 1 and 6 were treated with respect to Griffiths et al. in a manner similar to that noted with respect to Mattson above. Namely, the reference was used to reject the claims even though it is admittedly silent (i.e., does not teach) all of the claim limitations. In this regard, the Examiner specifically recognized that the nulling spectrometers in the reference was developed/used with samples having low concentrations (i.e., high transmissivity) due to poor signal-to-noise ratio issues.

But, the reference goes further. According to the reference, the techniques developed were thought only feasible with high transmissivity samples.⁴ As such, the Examiner's theoretical treatment of the situation on pages 8 and 9 of his Answer is thought to be completely irrelevant and amounts to hindsight reconstruction when one gives any credence to the teaching of the reference (which considers the signal-to-noise issue significant). Appellants assert that this fact should not be ignored as it is believed to have been in effort to support various rejections.

In view of the admission by the Examiner noted above and the text of the reference itself, it is believed to be abundantly clear that the reference is indeed limited to nulling interferomic spectrometers provided or used in connection with samples of high transmissivity. For this reason alone, the claims are believed allowable.

Even if the reference were not so-limited, the reference it still very clearly fails to disclose devices used with samples of low transmissivity as required by the claims. Therefore, as above with respect to the treatment of Mattson et al., the supposed generic teaching of the reference fails to support a §102 rejection of the low-transmissivity sample species practice of the present invention. Accordingly, the same arguments made above and requirement that the Examiner provide a cogent legal basis or reasoning for rejecting the claims in view of the reference (that does not specifically disclose the claimed invention) should apply. Pending such a

⁴ Again Appellants note page 285, where the reference states that the dual beam technique described was developed to allow "an interferogram to be measured that is due only to the small amount of radiation absorbed by the sample"

showing, which Appellants do not believe possible, the claims are believed to be allowable.

D. Examiner Treatment to Assertion of "Obvious to Try" Rationale Applied to Griffiths et al.

The Examiner refuted Appellants' assertion that the rejection of claims 14-20 were premised on an "Obvious to Try" rationale. In support of the rejection it was stated that Griffiths is silent on specific samples and analyzed because it would have been obvious to test for any analyte which has an absorbance spectrum within the spectrum of the infrared source. In so-saying, Appellants believe that the Examiner has merely restates his conclusion – without support. Importantly, the Examiner's comments give no treatment of the argument made in Appellants' Brief that the reference considered treatment of just any sample to be impractical and the subject of problems that prohibit "the full advantages of the technique to be realized in practice." As such, without some showing (accounting for the full teachings of the reference) that there would be some expectation of success, the rejection is believed improper.

E. No Motivation Supplied for Griffiths et al. Modification

The assertions in Appellants' Brief regarding a lack of expressed motivation do not appear to have been addressed by the Examiner. So answered, it is believed that Appellants arguments in this regard should prevail.

F. Hindsight Reconstruction Involving Griffiths et al.

The assertions in Appellants' Brief regarding use of hindsight reconstruction do not appear to have been addressed by the Examiner. Unanswered, it is believed that Appellants arguments in this regard should prevail.

V. Conclusion

The pending claims describe a system and methods for testing analyte concentration in a sample of low transmissivity which is not taught in the prior art. As discussed above Mattson et al. and Griffiths et al. fail to teach every aspect of the present invention. Further,

absent impermissible hindsight reconstruction, application of obvious to try rationale, or detrimentally affecting the utility of Griffiths et al. obviousness rejections are untenable. Accordingly, Appellants respectfully request that all rejections of the claims be withdrawn and that the application be allowed.

Respectfully submitted,

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APPENDIX

The Appealed Claims

1. A method of determining the concentration of an analyte in a sample of low transmissivity, said method comprising:
 - providing a sample of low transmissivity;
 - producing a sample beam from said sample of low transmissivity and a reference beam from a reference;
 - producing a null signal from said sample and reference beams; and
 - deriving the presence of said analyte in said sample of low transmissivity from said null signal.
2. The method according to Claim 1, wherein said method comprises using forward and backwards beams produced from at least one infrared radiation source to produce said sample and reference beams.
3. The method according to Claim 1, wherein said method further comprises passing light through an interferometer.
4. The method according to Claim 1, wherein said forward and backward beams are produced from a single infrared radiation source.
5. The method according to Claim 1, wherein said forward and backward beams are produced from two infrared radiation sources.
6. (Amended) A method of determining the concentration of an analyte in a sample of low transmissivity, said method comprising:
 - providing a sample of low transmissivity;
 - producing a sample beam from said sample of low transmissivity and a reference beam from a reference using forward and backward beams produced from at least one infrared radiation source;

producing a null signal from said sample and reference beams; and
deriving the presence of said analyte in said sample of low transmissivity from
said null signal;

wherein each of said beams pass once through an interferometer.

7. The method according to Claim 6, wherein said forward and backward beams
are produced from a single infrared radiation source.

8. The method according to Claim 6, wherein said forward and backward beams
are produced from two infrared radiation sources.

9. The method according to Claim 6, wherein said null signal is optically
produced by combining said sample and reference beams prior to detection at a
single detector.

10. The method according to Claim 6, wherein said null signal is electronically
produced following detection of said sample and reference beams at two separate
detectors.

11. (Amended) The method according to Claim 6, wherein said method further
comprises:

producing a forward beam and a backward beam with an
interferometer from a single infrared radiation source;
directing said forward beam into said sample of low transmissivity and
directing said backward beam into a reference and collecting a sample beam
and a reference beam, respectively;
combining said sample and reference beams to produce a nulled beam;
detecting said nulled beam with a single detector to obtain a detected null
signal; and
deriving the presence of said analyte in said sample of low
transmissivity from said detected null signal.

12. (Amended) The method according to Claim 6, wherein said method further comprises:

producing a forward beam and a backward beam from at least one infrared radiation source;

directing said forward beam through said sample of low transmissivity and directing said backward beam through a reference to produce a sample beam and a reference beam, respectively;

introducing said sample and reference beams into an interferometer and producing a null signal from said sample and reference beams following their exit from said interferometer; and

deriving the presence of said analyte in said sample of low transmissivity from said null signal.

13. The method according to Claim 6, wherein said sample of low transmissivity is at least one of highly reflective and highly absorptive.

14. The method according to Claim 13, wherein said sample is a physiological sample.

15. The method according to Claim 14, wherein said physiological sample is selected from the group consisting of blood, tissue, or a derivative thereof.

16. (Amended) The method according to Claim 14, wherein said reference comprises water.

17. The method according to Claim 16, wherein said reference is a fluid.

18. The method according to Claim 16, wherein said reference is a solid.

19. The method according to Claim 6, wherein said reference has a variable pathlength.

20. The method according to Claim 6, wherein said analyte is glucose.

21. (Amended) A dual beam infrared spectrometer system for use in determining the concentration of an analyte a sample of low transmissivity, said system comprising:

means for producing a forward beam and a backward beam from at least one infrared source;

means for producing a sample beam and a reference beam from said forward and backward beams; and

means for producing a null signal from said sample and reference beams.

22. (Amended) The system according to Claim 21, wherein said device system further comprises an interferometer means.

23. (Amended) The system according to Claim 21, wherein said device further comprises a means for deriving said analyte concentration from said null signal.

24. (Amended) The system according to Claim 21, wherein said system further comprises a reference.

25. (Amended) The system according to Claim 24, wherein said reference is a variable path length reference.

26. (Amended) The system according to Claim 24, wherein said reference comprises a liquid.

27. (Amended) The system according to Claim 24, wherein said reference comprises a solid.

28. (Amended) The system according to Claim 21, wherein said system further comprises a sample of low transmissivity.